

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)
Majid MEHTALI et al) Group Art Unit: Unassigned
Application No.: TBA) Examiner: Unassigned
(CIP of 09/463,486))
Filed: Even Date Herewith)
For: CHIMERIC ADENOVIRAL VECTORS)

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to examination, please amend the above-captioned application as follows:

IN THE CLAIMS:

Kindly replace claims 5-6, 8-9, 11, 13-14, 20, 24, 28-30, 32, 34 and 35, as follows:

5. (Amended) The method of claim 3, wherein said first and/or second helper adenoviral vector is (are) a wild-type adenovirus genome(s).
6. (Amended) The method of claim 3, wherein said first and/or second adenoviral vector is (are) a defective mutant(s) of a wild-type adenovirus genome.

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8. (Amended) The method of claim 6, wherein said first helper adenoviral vector is defective for E1 function.

9. (Amended) The method of claim 6, wherein said first helper adenoviral vector is defective in E2 function.

11. (Amended) The method of claim 6, wherein said second helper adenoviral vector is defective for E1 function and optionally E3 function.

13. (Amended) The method of claim 1, wherein said second adenoviral vector is functional for the E1 function and wherein the E1 region is placed under the control of a non-adenoviral promoter.

14. (Amended) The method of claim 1, wherein said first and second adenoviral helper vectors have an origin of replication recognized by the same E2-encoded gene products.

20. (Amended) The method of claim 1, wherein said first cell line is a non-human cell line.

24. (Amended) The method of claim 1 wherein said second cell line is of human origin.

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28. (Amended) The method of claim 1, which comprises more than one amplification step, wherein said viral particles obtained in step (f) are used to reinfect said second cell line in the presence of fresh second adenoviral helper vector or virus.

29. (Amended) The method of claim 1, which further comprises a purification step of the viral particles obtained in step (f).

30. (Amended) The method of claim 1, wherein said viral particles obtained in step (f) are substantially helper-free.

32. (Amended) A viral preparation obtained according to the method of claim 1, wherein said viral preparation is substantially helper-free.

34. (Amended) A pharmaceutical composition comprising a viral preparation according to claim 32.

35. (Amended) A method for the treatment of disease by gene therapy or immunotherapy comprising administering an effective amount of the viral preparation according to claim 32 to a patient in need of such treatment.

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REMARKS

Entry of the foregoing amendments is respectfully requested.

Should the Examiner have any questions concerning the subject application, a telephone call to the undersigned would be appreciated.

Respectfully submitted,

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Attachment to Preliminary Amendment dated May 31, 2001

Marked-up Claims 5-6, 8-9, 11, 13-14, 20, 24, 28-30, 32, 34 and 35

5. (Amended) The method of [any preceding claims] claim 3, wherein said first and/or second helper adenoviral vector is (are) a wild-type adenovirus genome(s).
6. (Amended) The method of [any preceding claims] claim 3, wherein said first and/or second adenoviral vector is (are) a defective mutant(s) of a wild-type adenovirus genome.
8. (Amended) The method of claim 6 [or 7], wherein said first helper adenoviral vector is defective for E1 function.
9. (Amended) The method of [any of claims 6 to 8] claim 6, wherein said first helper adenoviral vector is defective in E2 function.
11. (Amended) The method of [any of claims 6 to 10] claim 6, wherein said second helper adenoviral vector is defective for E1 function and optionally E3 function.
13. (Amended) The method of [any preceding claims] claim 1, wherein said second adenoviral vector is functional for the E1 function and wherein the E1 region is placed under the control of a non-adenoviral promoter.

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Marked-up Claims 5-6, 8-9, 11, 13-14, 20, 24, 28-30, 32, 34 and 35

14. (Amended) The method of [any preceeding claims] claim 1, wherein said first and second adenoviral helper vectors have an origin of replication recognized by the same E2-encoded gene products.

20. (Amended) The method of [any preceeding claims] claim 1, wherein said first cell line is a non-human cell line.

24. (Amended) The method of [any preceeding claims] claim 1 wherein said second cell line is of human origin.

28. (Amended) The method of [any preceeding claims] claim 1, which comprises more than one amplification step, wherein said viral particles obtained in step (f) are used to reinfect said second cell line in the presence of fresh second adenoviral helper vector or virus.

29. (Amended) The method of [any preceeding claims] claim 1, which further comprises a purification step of the viral particles obtained in step (f).

30. (Amended) The method of [any preceeding claims] claim 1, wherein said viral particles obtained in step (f) are substantially helper-free.

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Marked-up Claims 5-6, 8-9, 11, 13-14, 20, 24, 28-30, 32, 34 and 35

32. (Amended) A viral preparation obtained according to the method of [any preceeding claims] claim 1, wherein said viral preparation is substantially helper-free.
34. (Amended) A pharmaceutical composition comprising a viral preparation according to claim 32 [or a host cell according to claim 33].
35. (Amended) [Use of a viral preparation according to claim 32 or a host cell according to claim 33 for the preparation of a medicament] A method for the treatment of disease by gene therapy or immunotherapy comprising administering an effective amount of the viral preparation according to claim 32 to a patient in need of such treatment.

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